

The PASS Study

A Community Report

Prepared by the
Canadian Treatment Action Council



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About This Document

The **PASS Study: A Community Report** is a plain-language report on the Canadian Treatment Action Council's *PASS Study* – an investigation of community-based systems for reporting adverse reactions to approved medications.

Related Documents

A short (4-page) description of the PASS Study:

- **The PASS Study: A Brief Overview**
(CTAC fact sheet; March 2006)

Background: the current Canadian reporting system for adverse drug reactions:

- **How We Came To This PASS: The Current Post-Approval Surveillance System in Canada** (CTAC backgrounder; March 2006)
- **Improving our Health: The Need to Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada**
(CTAC discussion paper; December 2000)

(All of the preceding documents are downloadable in PDF format from the CTAC website, www.ctac.ca, in English and in French.)

The full, formal PASS study research report:

- **The PASS Study: Community-Based Reporting of Adverse Events from Anti-HIV Drugs**
(Mark Tyndall, Calvin Lai, and Francisco Ibáñez-Carrasco; July 2004)

(Available on request; English only.)

About CTAC

The **Canadian Treatment Action Council** (CTAC) is a national, non-governmental organization directed by people living with HIV/AIDS. CTAC informs public policy and promotes public awareness on treatment access and health care issues that impact people living with HIV/AIDS.

What is a Post-Approval Surveillance System?

Antiretroviral drugs are a compromise: they can be very effective at controlling HIV and the progression of HIV disease, but often at the price of toxicities and side effects. Such so-called *adverse reactions* or *adverse drug events* can range from bothersome (e.g., nausea, diarrhea, skin rashes) to potentially serious or even life-threatening (e.g., liver and kidney toxicities, diabetes and heart disease). The threat of these reactions (also including lipodystrophy – a sometimes disfiguring rearrangement of body fat) makes many people with HIV/AIDS (PHAs) reluctant to go on treatment.

Adverse Drug Event (ADE): a suspected, unwanted or harmful reaction to a drug.

The art of HIV treatment lies in maximizing benefit when weighed against the risks. In order to do that, we need accurate and complete information about drug benefits and adverse effects – both short-term and long-term. Drug approval decisions are based on relatively short-term information gathered during clinical trials. However, adverse effects continue to appear after drugs go to market. (Lipodystrophy, for example, did not receive much attention during the earliest protease inhibitor trials; only after multi-drug therapy had been in widespread use for years.) Health Canada describes the situation as follows:

All health products carry risks and benefits. Many of these risks are identified in pre-market testing and can be managed as “expected” or “tolerable” side effects that are outweighed by the product’s benefits. However, once a product is made available on the Canadian market, new “unexpected” or undesirable side effects, referred to as “adverse reactions”, are sometimes discovered when the product is used in “real world” conditions.¹

To continue to monitor adverse drug effects after approval, and to maintain an up-to-date knowledge base, Health Canada maintains a Post-Approval Surveillance System (PASS). There are significant gaps and shortcomings in the current PASS system. Canada’s current PASS is an essentially passive system that relies on health care professionals and pharmaceutical companies to take the initiative in reporting, and does not encourage active participation by people actually taking medications.

Post-Approval Surveillance System (PASS): a system to monitor serious drug side effects after the drug is approved for marketing.

CTAC’s position is that more active post-approval surveillance of approved drugs is necessary. (See related background documents on opposite page.)

¹ Health Canada website (Drugs & Health Products – Adverse Reaction Information): http://www.hc-sc.gc.ca/dhp-mpps/advers_react_neg/index_e.html

What is the PASS Study?

Having identified community-driven post-approval drug surveillance as one of its goals, CTAC chose to bring a *community-based research* approach to the issues of PASS. Community-based research (CBR) has many definitions, but it is generally recognized as:

“a collaboration between community groups and researchers, exploring practical issues with the goal of creating change.”²

This makes CBR different from much ‘traditional’ research, which is conducted by academic researchers for academic purposes, and may not involve the infected/affected community except as study participants or “subjects”.

In 1998, CTAC began a consultation between:

- CTAC Council members,
- community researchers,
- pharmacists,
- HIV primary care physicians,
- pharmaceutical industry representatives, and
- representatives of the Branches of Health Canada that regulate and monitor drugs.

These collaborators agreed that CTAC would collaborate with professional researchers to design and carry out a study of community-based information collection methods for a post-approval surveillance system of anti-HIV drugs in Canada.

Study Objectives

The CTAC PASS Study had four linked objectives:

- To pilot test four national methods of community-based data collection for antiretroviral side effects:
 - a toll-free 1-800 number,
 - face to face interviews,
 - mail/fax-in forms, and
 - focus groups.
- To compare the numbers of new reports of antiretroviral drug related events (over time, by location, and between data collection methods).
- To explore a ‘qualitative’ focus group method of collecting data (for specific ethnic/cultural groups – in this case, Aboriginal peoples).
- To report results to key stakeholders.

² Hills, M., & Mullett, J. (2000, May). *Community-Based Research: Creating Evidence-Based Practice for Health and Social Change*.

Gathering The Information

Research studies usually use one of two general methods: “quantitative” or “qualitative” (see Appendix - Key Terms). The PASS Study took a “mixed methods” approach which combined these two methodologies. This allowed for the measurement of data such as specific ADEs, while allowing flexibility in getting responses that might not lend themselves to rigid measurement.

There is an important distinction to be made: the PASS Study was mainly meant to evaluate *methods* for collecting post-approval drug information, not primarily the information itself. Although a considerable amount of clinical information on ADEs was gathered and analyzed, this was not the study’s main focus at this point. This pilot study emphasized the “hows” of gathering data, rather than the “whats”.

Four separate community-based methods were used to gather information:

- A **bilingual toll-free phone line** that operated during nation-wide office hours (Jan 03 –Jun 03).
- A **mail/fax-in** option: Data Collection Forms (see below) were widely distributed to AIDS community agencies across Canada. Participants could pick these up, fill them out, and either mail them in postage-paid envelopes or fax them (toll-free) to the data collection site (Jan 03 – Jun 03).
- **Face-to-face/one-on-one interviews** at AIDS community agencies in Toronto, Vancouver, and Montreal (Nov 02 – Feb 03).
- Four **focus groups** with Aboriginal people in rural and urban areas of British Columbia, Alberta, Manitoba, and Ontario (Jan 03 – Mar 03).

A standard Data Collection Form (DCF) was developed for the study, comparable to the form used by Health Canada’s PASS system. This DCF was used for the phone, fax, mail, and in-person methods. Adapted versions of the DCF questions were used for the focus groups.

Questions covered the following areas:

- Demographics
- The adverse event
- Effect of the event on the person living with HIV/AIDS
- Steps taken to treat the event
- Medication history
- Qualitative information on the impact of the event

The DCF was pilot tested in November 2002 in a focus group in Vancouver, and revised for clarity. (The final DCF is shown in Appendix B of the full PASS Study research report, *The PASS Study: Community-Based Reporting of Adverse Events from Anti-HIV Drugs*.) Unlike many other HIV/AIDS research studies, no honoraria (payments) were offered to the PASS Study participants, except for the focus groups; participants were informed of this. This reflected the current ‘real-life’ scenario in which consumers do not receive payment for reporting ADEs to Health Canada.

The collected data was sent to the research team at the BC Centre for Excellence in HIV/AIDS, where it was coded and analyzed. Wherever possible, coding was done using standard research toolkits and classification schemes.

Terminology – ADEs and ADRs

Definitions of the terms “adverse drug reactions” (ADRs) and “adverse drug events” (ADEs) overlap somewhat, but they are not interchangeable. Briefly, ADEs are *suspected* drug reactions; ADRs are confirmed “noxious responses to a drug” that “occur within a short-term of administering a drug”. (See Appendix – Key Terms.)

These definitions were written into the PASS DCF form in a plain-language adaptation as follows: “An *Adverse advent* [sic] is a negative, unexpected response to a drug when taken as prescribed by your doctor. The event might range from short-term discomfort to serious reactions that require treatment in hospital”.

Gathering The Participants

Publicity & Recruitment

AIDS service organizations (ASOs) were chosen as a natural point of contact, since a great many PHAs make contact with ASOs even if they do not extensively use their services. The study was advertised via a national campaign in the public media, and through local ASO communications routes, including:

- flyers faxed to 180 organizations,
- poster distribution,
- material on websites, and
- two rounds of advertisements in local newspapers³ (Nov 02 & Mar 03).

Upswings in phone calls were seen in March 2003, indicating that people did indeed respond to the ads.

Who Participated?

One measure of success is how well respondent demographics (sex, ethnic background, and geographic distribution) match up with the actual distribution of reported HIV/AIDS cases. Ideally, there should be similar proportions of men, women, and ethnic groups in the study population, as compared to the HIV+ population as a whole. The same should be true for where people are located geographically, and for how they were exposed to HIV (if known).

In fact, this turned out to be largely the case: the demographics of the PASS Study respondents are very close to the demographics of HIV/AIDS in Canada in most respects

³ (*Xtra-West* and *The Georgia Straight* in Vancouver, *Swerve* in Winnipeg, *The Coast* in Halifax, *See Magazine* in Edmonton, *XTra* and *Now Magazine* in Toronto, and the *Mirror* and *Voir* in Montréal.)

except geography. Geographically, PASS Study responses did not completely reflect the national distribution of HIV/AIDS cases; more responses were collected in the provinces (British Columbia, Ontario, and Quebec) where face-to-face interviews took place.

The following tables show the demographics of the study as a whole, and of the different response methods, compared to the 2002 Canadian reported demographics.

Table 4.1: Reporting method by gender

	Interviews	Mail/Fax	Phone	Total
Male	779: 83.5 %	80: 82.5%	35: 87.5%	894: 83.6%
Female	125: 13.4%	11: 11.3%	5: 12.5%	141: 13.2%
Transgendered	8: 0.9%	0: 0.0%	0: 0.0%	8: 0.7%
Two-Spirits	21: 2.3%	6: 6.2%	0: 0.0%	27: 2.5%
TOTAL	933	97	40	1070

Reported Canadian HIV/AIDS cases by gender: approx. 85.2% male, 14.8% female.

Table 4.2: Reporting method by ethnicity

	Interviews	Mail/Fax	Phone	Total
White	608: 65.2%	59: 60.8%	34: 85.0%	701: 65.5%
Aboriginal	91: 9.8%	14: 14.4%	0: 0.0%	105: 9.8%
Black	36: 3.9%	2: 2.1%	0: 0.0%	38: 3.6%
Asian	29: 3.1%	1: 1.0%	1: 1.0%	31: 2.9%
Hispanic	26: 2.8%	0: 0.0%	0: 0.0%	26: 2.4%
Other	143: 15.3%	21: 1.6%	5: 12.5%	169: 15.8%
TOTAL	933	97	40	1070

Reported Canadian HIV/AIDS cases by ethnicity: approx. 15% Aboriginal, 57% Caucasian.

Canadian HIV/AIDS Statistics

Canadian HIV/AIDS stats are available through Health Canada's "Surveillance Reports" and "Epi Updates", online at:

www.phac-aspc.gc.ca/publicat/epiu-aepi/index.html

Table 4.3: Reporting method uptake by province

	Interviews	Mail/Fax	Phone	Total
BC	571	13	1	585
Quebec	263	12	10	285
Ontario	98	32	20	150
Nova Scotia	0	12	6	18
Manitoba	0	6	2	8
New Brunswick	1	6	0	7
Saskatchewan	0	6	0	6
Alberta	0	5	0	5
PEI	0	4	1	5
NFLD/Labrador	0	1	0	1
TOTAL	933	97	40	1070

PASS Study respondents generally reflected the national distribution in other characteristics (such as proportion of injection drug users).

Comparing The Reporting Methods

The responses to the various reporting methods were widely different. Overall, the most resource-intensive methods worked the best: one-on-one interviews gathered by far the greatest number of responses, and the data gathered was of high quality. The focus groups were similarly successful. The toll free phone line was not used as much as anticipated. Mail and fax were not well-used.

Interviews

Each participating ASO hired one-on-one interviewers who had an established local presence – someone participants would be likely to know or have heard of, and trust as a “peer”. Interviewers (and focus group leaders) were generally men and women living with HIV/AIDS themselves, and/or treatment activists known within their communities. Interviewers were trained by study investigators.

Study advertising was helped along by awareness campaigns at the ASOs themselves, and through word-of-mouth. Since it was important to get participants from a wide range of social and economic backgrounds (from very vulnerable populations, such as street-based IDUs, to employed professionals), participants included users of a wide range of ASO services. Interviews were done at the “base” ASO and other related sites, again to ensure a broader variety of participants

In the actual interviews, participants were told what the study was about, and invited to fill out the Data Collection Form with the help of the interviewer.

A total of 933 participants completed Data Collection Forms in one-on-one interviews over the duration of the study. Out of the different reporting methods, the one-on-one interviews worked best at getting respondents' attention, and at getting high quality responses. Interviews were seen as **credible**, **convenient**, and **helpful**, because:

- Participants were approached in familiar surroundings, in a non-intimidating way.
- The interviewers were locally “familiar faces”, presumably seen as trustworthy.
- Interviewers clarified questions and helped with any difficulties arising from literacy.

One significant limitation of the community setting is that it requires great staff training and output. (Also, some PHAs are not comfortable visiting ASOs.)

Interviews in a medical setting (hospital clinic) were successful because health care professionals are **credible** and could promote the study directly. The limitation of the medical setting is that uptake depends on the time of the day interviewers are available, and adds to the workload of the partnering health care professionals.

Telephone Line

Interviewers were trained to staff a toll-free 1-800 line that could be reached from across the country during normal office hours. Telephone interviewers were trained in basic medical terminology and medicines, and were given visual charts of antiretroviral medications to help callers who could not remember the names of pills. The interviewers also developed a “script” to engage callers in a non-intimidating way.

The toll-free line was a very resource-intensive option, requiring bilingual interviewers to cover 12.5 hours per day to cover business hours in all time zones. It was also difficult to house: space had to be solicited from other non-profit organizations, many of which are already strapped for space. Many organizations were concerned with potential liability and ethical issues arising from callers in immediate distress or medical danger.

The number of calls to the toll-free phone line was very small – only 40 surveys were completed – even though the line operated continuously for six months at considerable cost. We cannot conclusively say why the phone line usage was so poor.

Fax and Mail

A total of 1,755 mailable/faxable Data Collection Forms were sent to 120 AIDS service organizations (ASOs) nation-wide (1510 in English and 245 in French). These were placed in visible locations in ASOs where service users could readily pick them up. Of these, only 97 completed forms were received.

Although the mail/fax method appears to be the “simplest” and least expensive method, it actually had a very low uptake. (However, PHAs did use the mail/fax method to respond

outside the areas where personal interviews were conducted.) The problem may have been that the fax- and mail-reporting methods are the most passive.

The data gathered from the mailed/faxed-in forms was not always as clear or complete as the data from the interviews, since no interviewers were available to ask clarifying questions if necessary.

Aboriginal Focus Groups

Focus groups are settings in which small groups of participants (typically a dozen or less) come together to discuss issues under the guidance of one or more trained facilitators. Many ASOs have used focus groups as flexible tools to provide data for community-based research and review their own programs.

The PASS Study focus groups were advocated and vetted by Aboriginal people who were partners in the research from the outset. The focus groups served to gather information for the project, share knowledge between participants, and provide a degree of personal support. An Aboriginal Elder was included, to acknowledge the communal approach at the heart of Aboriginal experiences. The focus group leaders received an orientation from researchers and a First Nations member from the PASS Advisory Committee, and agreed collectively on how to adapt the standard Data Collection Form questions to a format that would work in the focus group setting.

Focus group leaders, with the help of a local Elder, identified and invited potential participants. A “snowball” sampling strategy was used: the researcher and the local Elder gathered respondents known to them, who were encouraged to bring other people into the groups, and so forth. The leaders then organized the focus groups in the traditional manner of talking circles, with blessings and food offerings.

The focus groups gathered a total of 22 participants - nine females and thirteen males (six self-identified as two-spirited) between the ages of 24 and 63. Focus groups leaders collected demographic information, but ensured anonymity by omitting names. The leaders also produced detailed verbal and written reports that included full transcripts of the focus groups.

The focus groups were successful in collecting information by fitting in well with the existing “social ecology” of the respondents. Most focus group leaders found it fairly easy to recruit and engage people in their groups. It was also reported that focus groups became a place for new information sharing and support. Aboriginal women felt especially comfortable to participate in research and report private information in this manner.

What Did People Say?

Participants reported their ADEs on a standard Data Collection Form similar to the existing Health Canada Adverse Drug Reaction Reporting Form. Respondents were asked to focus on “the most serious adverse drug event” they could recall (the time frame was left open).

The PASS Study was primarily meant to investigate *ways of collecting* ADE information. This naturally meant collecting actual ADE information from the participants, but this information itself is actually secondary to the real purpose of the study.

Quantitative, or measurable data on specific experiences, is described in the formal research report. In general, descriptions were consistent with accepted pharmacological profiles of the actual drugs being taken. Some key (numeric) findings were as follows:

- Nine hundred and ninety-six (93%) respondents reported one or more adverse events.
- Most participants (942 — 88%) reported their ADE to at least one health professional.
- When asked to describe adverse events, 968 informants offered replies.
- Three hundred and fifty-five (36%) respondents reported taking medical steps to deal with the ADE, including over-the-counter medications, switching drugs or adjusting the dosage.

The qualitative questions in the Data Collection Form were the following:

- Q# 9 — “Describe what this adverse event was”,
- Q#14 — “What did you do [to treat symptoms of ADEs]?”,
- Q#19 — “How has this event affected your life?” and
- Q#20 — “Add more information that you think may be important.”

As far as the terminology used to report symptoms, the language ranged from self-reporting in technical medical terms, to much less technical “layperson terminology”. This indicates that, on one hand, participants were keenly interested in their own health and often had a high level of technical literacy regarding HIV drugs. On the other hand, sometimes important distinctions were misunderstood, such as when people reported illnesses (e.g. herpes) as side effects.

Canadian research on HIV disease is increasingly referring to HIV disease as an “episodic illness” – one with ups and downs, good and bad days. People living with the disease often experience it as a “roller coaster”, going from periods of health and well-being to episodes of sickness, difficulty and turmoil. HIV positive people in general are living longer, re-organizing their lives, and re-inventing themselves. However, people often do this work – which they often refer to as “a full time job” – while facing old stigmas and fighting new battles.

These experiences are summed up in a quotation from another study that looked at the way PHAs manage their medications:

“...[T]he work people do to manage their medications is not done in isolation, but is very much a social practice that necessarily connects PHAs to friends, doctors, clinics, ASOs, pharmacists, drug companies, information sources, and a variety of other service providers.”

Making Care Visible (2002).

The qualitative answers to the PASS Study reflect this struggle, and show that community-based reporting is a way to collect and report on the *lived experience* of PHAs through the methods of clinical reporting. The following participant quotes say a lot about how many PHAs feel about adverse antiretroviral drug reactions:

“I wish they could tell us more when they put us on a new drug; of course the prescription is accompanied with a couple of pages of information, but it all seems [incomprehensible] until it kicks in; it is a real roller coaster at times, physically and emotionally”.

50 year old male respondent from Toronto—mail response to PASS DCF, March 2003.

“I feel paranoid about taking the [anti-HIV] drugs. [...] I feel that there should be more emotional support and not ‘the number game’—for example, they say, ‘your blood work is good, you can go home!’”

37-year-old Caucasian female interviewed at BCPWA in January 2003.

Out of 1070 individuals, 964 responded to question #19 (“*How has this event affected your life?*”). The answers were coded into eight categories, ranging between “not affected” to “permanently” affected. (The latter means permanent disability, inability to work, and/or use of external physical support, such as guide dogs, scooters, or canes.) Two additional codes were also added: “psycho-social impact” (broadly capturing mental health issues, stigmatization and poverty), and “issues of adherence and compliance”. Results were as shown in Table 4.3:

Table 4.3: Range of impact of adverse events

Range of Impact	N (number)	%
Positively affected	74	8%
Not affected	41	4%
Minimally affected	140	15%
Partially	310	32%
Negatively	92	10%
Permanently	57	6%
Psychosocial impact	195	20%
Affected adherence	55	6%
TOTAL	964	

Table 4.3 shows how severely ADEs affected lifestyle, well-being, mental health, attitude towards medication, and physical activity. As shown, antiretrovirals have affected a large percentage of the population of this study.

One participant expressed the defining quality of HIV disease and his views toward medications in the following dramatic way:

“I lost a full time career, an apartment, I went bankrupt, faced drug addiction, and acquired a victim status [...] I was lucky though, I opted to strive for quality of life versus quantity. I have taken no medications since 1993. They were killing me.”

43 year old Caucasian male, interviewed at “Friends For Life” in Vancouver, B.C., January 2003.

The answers to question #20 (“any more information”) range from detailed explanations about medications, to angry remarks about pharmaceutical companies or health care professionals. They count as evidence of growing “treatment fatigue” amongst people living with HIV.

One participant stated,

“I had physical pain. I had fear. [...] Doctors only give us parts of the information we need. It is up to us to find the rest of the necessary information.”

50 year old Caucasian male, interviewed in Montreal on March 2003.

Also mentioned were: emotional (“affective”) and mental health challenges brought on by anti-HIV medications, the differences between women and men when it comes to antiretroviral therapies, their side effects, and their meaning in the lives of women living with HIV. One female PHA stated,

“I have instability in my life. My social life has been affected. I am unable to work. [...] Research has been done mostly on men. Women are not considered differently than men.”

41 year old female respondent, Montreal, one-on-one interview.

One of the most significant findings of the PASS Study may be the poor fit between PHA lived experience and conventional clinical reporting. The existing Health Canada ADE reporting system does not provide room for this kind of qualitative, ‘lived’ information. The community-based approach and mixed methodology of the PASS Study allowed people to comment, not only on the specific biomedical symptoms they experienced, but how these symptoms affected their lives.

For instance, in question 9 (“Describe what this adverse event was”), people were likely to describe their experiences in plain, mostly impersonal, and often biotechnical terms. However, people expanded on their experiences in later questions. For example, many respondents mentioned suffering from lack of sleep, lack of appetite, and having gastrointestinal problems. The combination of these problems over a long period of time resulted in “social isolation” and “depression”.

It was sometimes difficult for people to disentangle ADEs (associated with medications) from the symptoms of HIV disease itself. This can be viewed in two ways. Medically, it is best to have “clean” data, which neatly separates biomedical from psychological and social issues, and drug toxicities from direct effects of HIV. (A database of drug reactions would not include social problems, or the fear and anxiety mentioned by some respondents.) However, from a community/PHA point of view, these distinctions are

often beside the point. People with HIV/AIDS have problems with medications that include physical, emotional, and social.

Summary: Strengths and limitations of qualitative reporting

- Community-based reporting, by including qualitative open-ended questions, is a useful tool alongside the current narrower clinical reporting.
- Community-based reporting sheds light on associations between clinical therapy and trust in clinicians, drugs, and their effects. It allows for discussion of therapies in a wider context that includes the social impact of antiretrovirals.
- The combination of clinical (quantitative) questions and open-ended (qualitative) questions needs to be reassessed carefully to provide future participants with a clear and useful way to use these mixed methods.
- Focus group interviewers raised the following issues:
 - Questions about HIV transmission (how people were infected) may be uncomfortable in a peer-driven setting.
 - When working with low income individuals, interviewers need a good knowledge of the “culture” in order to schedule visits (e.g. income assistance cheque issues days are low in attendance, food bank days register peak attendance).

What Next?

The PASS Study was conducted so that we could:

- observe how people living with HIV who use antiretroviral drugs use various reporting mechanisms,
- find what works or does not for them, and
- assess the quality of the ADE-related information funnelled through these reporting mechanisms.

The methods used were implemented as a “trial run”, to see what would happen if such community-based reporting systems were actually running. Therefore, the actual question, “*How would you prefer to report ADEs?*”, was not directly asked. From the study results, it is fairly clear which methods were most successful. However, a brief additional poll could also be done to actually ask PHAs and health care professionals what their preferred reporting method would be, and why.

The study showed that there was confusion between “illnesses”, “side effects”, “adverse drug reactions”, “serious drug reactions” and “adverse events”. This confusion seems widespread – it is present in medical literature and the existing systems, not just among PHAs. This confusion over terminology will affect the information collected. Any future reporting mechanisms should include an *educational* component and a *health literacy* component that address these issues.

The PASS Study suggests that community based reporting of ADEs could be successful in following the course of ADEs, side-effects, and contributing illnesses, as well as how people manage them. (The current system does not investigate how people manage their ADEs.) The information gathered should also be readily accessible to consumers and health professionals.

This community-based initiative provides important information on methods for collecting information on adverse events. Community-based reporting mechanisms should be able to capture a broader range of information directly from individuals taking medications, and may play an additional, significant role in a sustainable national reporting program for people living with HIV/AIDS.

Appendix: Key Terms

Adverse Drug Event (ADE) – A *suspected* unwanted or harmful reaction to a drug. According to Health Canada’s *Guidelines for Reporting Adverse Reactions to Marketed Drugs*⁴, an Adverse Event/Experience (AE) is “any untoward medical occurrence that may present during treatment with a pharmaceutical product but that does not necessarily have a causal relationship with this treatment.”⁵

Adverse Drug Reaction (ADR) – A *confirmed* unwanted or harmful reaction to a drug. An Adverse Drug Reaction (ADR) is “a noxious and unintended response to a drug which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function.”⁶

Antiretrovirals – Drugs used to control HIV.

ASOs – AIDS Service Organizations.

Clinical Trial – A study of drugs or other treatments in human participants. Trials can be divided into 4 phases:

- Phase I: The first trials to be done in human participants. Phase I trials are mostly aimed at finding any immediate or dire safety concerns, and finding the best doses to use in larger trials. Most often done in a few healthy volunteers.
- Phase II: Involve a few dozen to perhaps a few hundred people. These trials further investigate drug safety, and begin to study efficacy (how well it works).
- Phase III: The large-scale trials (hundreds to thousands of participants) that gather the bulk of the short-term safety and efficacy data, to be used for drug approval applications. Phase I, II and III trials all precede drug approval.
- Phase IV: Post-approval trials that study ongoing, longer-term safety and efficacy. Formal Phase IV trials are not often conducted once a drug has been marketed – hence the importance of other forms of post-approval surveillance.

Community-Based Research - Community-based research is a collaboration between community groups and researchers for the purpose of creating new knowledge or understanding about a practical community issue in order to bring about change. The issue is generated by the community and community members participate in all aspects of the research process. (*Hills & Mullett, 2000*).

Demographics – Characteristics that distinguish a group of people, such as gender, age, and ethnicity.

Efficacy – How well a drug works.

⁴ www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/guide-ldir_indust_e.html

⁵, ⁶ Same as above.

Mean – The arithmetic average of a set of numbers. (To find the mean of **n** numbers, add up all the numbers, then divide by **n**.)

Methodology – The specifics of the methods used to carry out a study.

PHA – Person living with HIV/AIDS.

Pilot Study – A small-scale study intended to show the workability of a research idea, and identify issues & problems to be solved in a full-scale study.

Qualitative Research – Research that explores unknowns and is more concerned with describing and telling stories, than measuring numbers (as compared to “quantitative” research). May identify trends that can later be explored by quantitative research.

Quantitative Research – Research that is concerned with measuring well-defined quantities and numbers. (E.g., how many people achieve undetectable viral load with a given drug combination.)